



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,456	03/15/2001	Henning Madry	0492611-0383	5208

7590 06/16/2004
Theresa A. Delvin, P.h.D
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, MA 02109-2891

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,456

Applicant(s)

MADRY ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-52 is/are pending in the application.
- 4a) Of the above claim(s) 22-42, 46 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4-21, 43-45, 47-50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 4, 5-52 are pending in the present application. Claims 1 and 3 have been cancelled. Claims 2, 4, 5-21, 43-45, 47, 48-50 and 52 are currently under consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 March 2004 has been entered.

Response to Amendment

In view of the amendment to now independent claim 10 the rejections of the claims are moot in favor of the rejections below.

Claim Objections

Claim 10 is objected to because of the following informalities: Collagen is listed twice in the list of second biocompatible materials. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1636

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 5-21 43, 44, 45, 47-50 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al. (US Patent No. 5,785,964) in view of Breitbart et al. (U.S. Patent No 6,077,987).

Naughton et al. teach a three-dimensional cell culture system for the formation of a construct comprising a biocompatible extracellular matrix and cells such as bone marrow, liver and pancreas cells. The method of Naughton et al. drawn to a three dimensional cell and tissue culture system included the use of three dimensional substrates such as collagen gel, cellulose sponge or a first matrix component, cellulose sponge, coated with a second matrix component, collagen. See abstract and column 2, lines 10-19. Naughton et al. teaches that the cells grown on a matrix may be cells transfected with exogenous nucleic acids. See e.g. column 49, lines 24-33. Naughton et al. also disclose that a matrix support may include polyesters, polystyrene, polypropylene, and polyglycolic acid, including matrices with a collagen coat. See column 8, lines 28-52.

Breitbart et al. disclose a method for making a tissue construct comprising cells transformed with a growth factor that are seeded onto a biocompatible matrix comprising either synthetic or non-synthetic materials. See column 3 and column 8, lines 35-67. Breitbart teaches that a variety of cells may be transformed and grown on an extracellular matrix. See col. 8, lines 35-37 and column 2, line 60. Breitbart et al. disclose the use of several growth factors such as platelet-derived growth factor, vascular endothelial growth factor, insulin-like growth factor, epidermal growth factor and fibroblast growth factor, for example. See column 3, lines 55-60.

Art Unit: 1636

Breitbart et al. fail to disclose that cells such as hepatocytes, Islet cells, and endothelial cells may be transfected and grown with an extracellular matrix such that a tissue engineered construct is formed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tissue engineering construct comprising transformed hepatocytes (liver cells), endothelial cells (bone marrow cells) or Islet cells (pancreas cells) and a biocompatible extracellular matrix. As taught by Naughton et al. these cell types may be adhered and proliferated on three-dimensional extracellular matrices because extracellular matrices provide a greater surface area for attachment and the adherence of cells. See column 7, line 60 to column 8, line 23. Moreover, Breitbart et al. disclose that a variety of cell types may be transfected and grown on three-dimensional matrices as well. See col. 8, lines 35-37 and column 2, line 60. Breitbart et al. also teach growth factors that are effective for various cell types including hepatocytes, endothelial cells, and Islet cells such as VEGF, IGF-1 and endothelial derived growth supplement. See column 3, lines 50-60. Given the teachings of the art, the ordinary skilled artisan would have been motivated to grow transformed hepatocytes, endothelial cells or Islet cells in the presence of appropriate growth factors on extracellular matrices. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-

Art Unit: 1636

0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Konstantina Katcheves
Examiner
Art Unit 1636